

i.e., a compound wherein:

R^1 , R^2 and R^6 each is H;

R^3 is indol-3-yl;

R^4 is $-C(O)-NH-CH(CH_3)-(CH_2)_3-N(\text{diethyl})$; and

R^5 is $-C(CH_3)_2-C(O)-NH-(CH_2)_6-NH-C(O)-O-CH_2\text{-phenyl}$

Applicants further provisionally elect the following method of use from claims 31-36: from claim 33, a method of binding one or more of a somatostatin subtype receptor in a subject in need thereof.

The present election is made with traverse.

REMARKS

As an initial matter, Applicants note that the present application is a national phase application of International Patent Application No. PCT/US99/12760 (WO 99/64401), and that unity of invention was not found to be lacking by the International Searching Authority. The Examiner does not indicate what errors the International Searching Authority implicitly is alleged to have made in arriving at this determination. Rather the Examiner rests the finding of non-unity on the alleged existence of prior art in respect of each of the proposed restriction groups, (see Instant Office Action, at page 3, 4th paragraph).

However, despite the Examiner's allegation of pertinent prior art, not a single prior art reference is actually cited. As such the allegation comprises a mere unsupported and conclusory statement. Further, since the Applicants have not been informed of the prior art considered by the Examiner to be relevant Applicants effectively have been foreclosed from mounting a

meaningful rebuttal on the merits. Applicants simply cannot critique the teachings of an unidentified reference.

Applicants respectfully submit that unity of invention is satisfied by the instant claims. Applicants direct the Examiner's attention to MPEP §1850, and to Annex B to the Administrative Instructions Under the PCT, from which the following relevant passages are excerpted (page numbers refer to the August, 2001 edition of the MPEP; emphasis added in all cases):

From §1850:

p. 1800-61, col. 1, para. 1:

Therefore, when the Office considers international applications as an International Searching Authority, as an International Preliminary Examining Authority, and during the national stage as a Designated or Elected Office under 35 U.S.C. 371, *PCT Rule 13.1 and 13.2 will be followed when considering unity of invention of claims of different categories without regard to the practice in national applications filed under 35 U.S.C. 111.*

p. 1800-61, col. 2, para. 1:

If the independent claims avoid the prior art and satisfy the requirement of unity of invention, *no problem of lack of unity arises in respect of any claims that depend on the independent claims.*

p. 1800-62, col. 1, para. 2-3:

The method for determining unity of invention under PCT Rule 13 shall be construed as *permitting*, in particular, the inclusion of any one of the *following combinations of claims of different categories* in the same international application:

(A) *In addition to an independent claim for a given product, [...] an independent claim for a use of the said product;*

p. 1800-62, col. 2, para. 2-4 and continuing to p. 1800-63:

When the Markush grouping is for alternatives of chemical compounds, they shall be regarded as being of a similar nature where the following criteria are fulfilled:

(A) All alternatives have a common property or activity; and
(B)(1) A common structure is present, i.e., a significant structural element is shared by all of the alternatives;

[...]

In paragraph (B)(1), above, the words "significant structural element is shared by all of the alternatives" refer to cases where the compounds share a common chemical structure which occupies a large portion of their structures, or in case the compounds have in common only a small portion of their structures, the commonly shared structure constitutes a structurally distinctive portion in view of existing prior art. The structural element may be a single component or a combination of individual components linked together.

[...]

The fact that the alternatives of a Markush grouping can be differently classified shall not, taken alone, be considered to be justification for a finding of a lack of unity of invention.

From Annex B:

Re: Claims in Different Categories

p. AI-57, Example 1:

Claim 1: A method of manufacturing chemical substance X.

Claim 2: Substance X.

Claim 3: The use of substance X as an insecticide.

Unity exists between claims 1, 2 and 3. The special technical feature common to all the claims is substance X.

p. AI-57, Example 4:

Claim 1: Use of a family of compounds X as insecticides.

Claim 2: Compound X1 belonging to family X.

Provided X1 has the insecticidal activity and the special technical feature in claim 1 is the insecticidal use, unity is present.

p. AI-60, Example 15:

Claim 1: Compound A.

Claim 2: An insecticide composition comprising compound A and a carrier.

Unity exists between claims 1 and 2. The special technical feature common to all the claims is compound A.

p. AI-60, Example 16

Claim 1: An insecticide composition comprising compound A (consisting of a 1, a 2...) and a carrier.

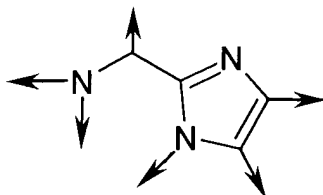
Claim 2: Compound a1.

All compounds A are not claimed in the product claim 2 for reasons of lack of novelty of some of them for instance. There is nevertheless still unity between the subject matter of claims 1 and 2 provided a 1 has the insecticidal activity which is also the special technical feature for compound A in claim 1.

Applying the rules of §1850 MPEP and the examples of Annex B to the instant claims it is readily apparent that unity of invention is satisfied.

First, all claimed alternatives, i.e., compounds, have a common property or activity: they are useful as somatostatin ligands.

Second, central to all of the compounds of the instant claims is the following "significant structural element":



Applicants respectfully submit that the foregoing moiety comprises a "significant structural element" of the claimed compounds under either criteria indicated at §1850 MPEP; i.e., it either occupies a large portion of a claimed structure or it constitutes a structurally distinctive portion of a claimed structure in view of the prior art. Regarding this latter criteria, as discussed, *supra*, no prior art has been cited in

support the Examiner's allegation the claims "lack the same or corresponding special technical features."

Further in this regard Applicants respectfully remind the Examiner of the admonition against basing a finding of lack of unity solely upon the possibility that the alternatives of a Markush group may be classified differently, (§1850 MPEP, p. 1800-63, col. 1.).

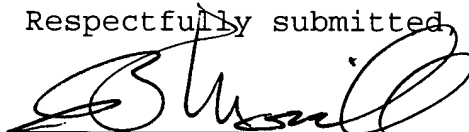
Regarding the claimed uses for the claimed compounds, all of the uses are related in that they all relate to the compounds' property of acting as somatostatin ligands. Thus a proper analogy may be drawn to example 4 at MPEP page AI-57, in which unity is found between claims to use of a family of compounds X as insecticides and a compound X2 belonging to family X. No doubt in this example unity would remain preserved in respect of an additional claim drawn to use of the family of compounds X to kill carpenter ants, wasps, houseflies, etc. The claim drawn to use of X as an insecticide is in effect a genus claim in respect of the claim drawn to use of X to kill a specifically enumerated bug.

Similarly regarding the instant use claims, a claim drawn to use of a compound of, e.g., formula (I) to bind a somatostatin receptor in a subject in need thereof (see claim 33) comprises in effect a genus in respect of a claim drawn to use of a compound of formula (I) to treat a specifically enumerated disease or condition (see claim 34). Thus unity remains preserved.

In view of the foregoing Applicants respectfully submit that unity of invention is satisfied by the present claims and therefore that concurrent examination of all claims is appropriate. Withdrawal of the restriction requirement is earnestly requested.

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Respectfully submitted



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